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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,248	03/29/2000	David A. Cheresch	TSRI-651.3	6166
2387	7590	12/15/2003	EXAMINER	
OLSON & HIERL, LTD. 20 NORTH WACKER DRIVE 36TH FLOOR CHICAGO, IL 60606			PROUTY, REBECCA E	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/538,248

Applicant(s)

CHERESH ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 5-15 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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In view of the appeal brief filed on 6/2/03, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claims 1-31 are still at issue and are present for examination.

Applicants' arguments filed on 6-2-03, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 5-15 and 21-31 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction/election requirement in the response filed 12-17-01.

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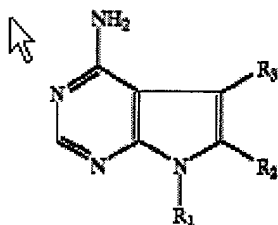
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al. (US Patent 6,001,839).

Calderwood et al. teach methods of treating diseases including VEGF mediated edema using tyrosine kinase inhibitors having the structure shown below (see column 13, lines 29-48).



These compounds are disclosed as inhibitors of tyrosine kinases including Src kinases (see column 12 line 53 - column 13, line 10). Calderwood et al. further teach pharmaceutical compositions of the disclosed compounds.

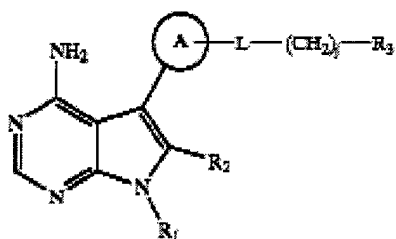
Thus Calderwood et al. anticipate all of the instant claims.

Claims 1, 2, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al. (US Patent Application 2003/0187001).

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Calderwood et al. teach methods of treating diseases including VEGF mediated edema using tyrosine kinase inhibitors

having the structure shown (see paragraph 56 and 101). These



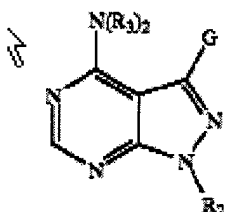
compounds are disclosed as inhibitors of tyrosine kinases including Src kinases (see paragraphs 53 and 111).

Calderwood et al. further teach pharmaceutical compositions of the disclosed compounds. Thus Calderwood et al. anticipate all of the instant claims.

Claims 1, 2, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirst et al. (US Patent Application 2002/0156081).

Hirst et al. teach methods of treating diseases including edema using tyrosine kinase inhibitors having the structure shown

(see paragraph 315 and 350). These compounds are disclosed as



inhibitors of tyrosine kinases including Src kinases (see paragraphs 311 and 349). Hirst et al. further teach pharmaceutical compositions of

the disclosed compounds. Thus Hirst et al. anticipate all of the instant claims. While the effective filing date of Hirst et al. (9/17/99) fall after some of the claimed priority dates of the

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instant application, none of the claimed prior applications teach the use of small organic chemical inhibitors of Src family tyrosine kinases for treatment of conditions related to vascular leakage or edema and neither PCT/US99/11780 nor provisional application 60/087,220 provide support for treatment of conditions related to vascular leakage or edema as is currently claimed. As such the instant claims have not been granted the benefit of the filing date of the prior applications.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

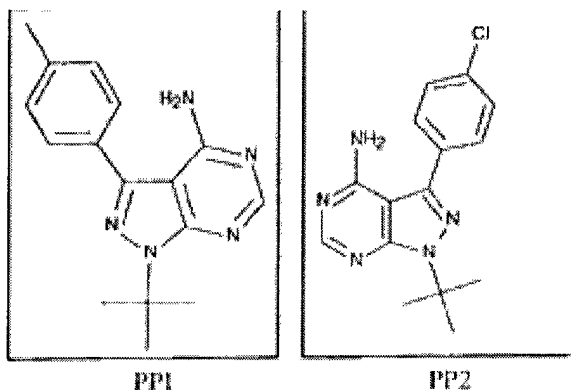
Claims 3, 4, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al (US Patent 6,001,839), Calderwood et al. (US Patent Application

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2003/0187001) and Hirst et al. (US Patent Application 2002/0156081) in view of Hanke et al.

Calderwood et al (US Patent 6,001,839), Calderwood et al. (US Patent Application 2003/0187001) and Hirst et al. are all discussed above. Each of the above teach the treatment of edema with tyrosine kinase inhibitors which inhibit tyrosine kinases including Src kinases. None of them specifically teach the use of the pyrazolopyrimidines PP1 or PP2 for the treatment of edema.

Hanke et al. teach the



pyrazolopyrimidines PP1 and PP2 having the structures shown.

Hanke teach that PP1 and PP2 are tyrosine kinase inhibitors which inhibit Src kinases. Hanke et al. do not teach the use of PP1 or PP2

to treat edema.

The structural similarity of PP1 and PP2 to the tyrosine kinase inhibitors of Calderwood et al (US Patent 6,001,839), Calderwood et al. (US Patent Application 2003/0187001) and Hirst et al. is readily apparent to a skilled artisan and these compounds are similarly disclosed as tyrosine kinase inhibitors which inhibit tyrosine kinases including Src kinases. As such it would have been obvious to one of skill in the art to use PP1 and

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PP2 to treat edema as taught by Calderwood et al (US Patent 6,001,839), Calderwood et al. (US Patent Application 2003/0187001) and Hirst et al. for the structurally and functionally similar tyrosine kinase inhibitors.

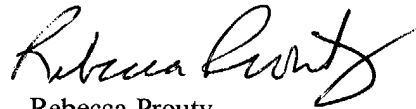
The previous rejections of the claims are withdrawn as after a review of the disclosures of Hayashi et al. and Bao et al. each teach away from the suggestion of the previously cited references that edema can be treated by inhibiting VEGF as Hayashi et al. teaches a reduction in edema following treatment with VEGF and Bao et al. teaches an increase in edema following treatment with a VEGF antibody. As such one of ordinary skill in the art would not have had a reasonable expectation that inhibiting VEGF signaling by inhibiting Src kinase would successfully treat edema as the effects thereof were not clear in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
Art Unit 1652



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SUPERVISORY PATENT EXAMINER
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